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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/088,814	09/04/2002	Andrew Austen Mortlock	ASZD-P01-599	2356
44992	7590	11/04/2005	EXAMINER	
ASTRAZENECA R&D BOSTON			TRUONG, TAMTHOM NGO	
35 GATEHOUSE DRIVE			ART UNIT	
WALTHAM, MA 02451-1215			PAPER NUMBER	

1624

DATE MAILED: 11/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/088,814

Applicant(s)

MORTLOCK ET AL.

Examiner

Tamthom N. Truong

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12 August 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 20,27,30 and 34-44 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 20,27,30 and 34-44 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### FINAL ACTION

Applicant's amendment of 8-12-05 has been fully considered.

The amended claim 20 has overcome the previous rejection of 112/2<sup>nd</sup> paragraph by deleting the limitations of "hydrocarbyl" as well as "heterocyclyl", and by listing moieties or rings intended for said limitations.

The cancellation of claims 19 and 29 has also overcome the previous rejection of 112/2<sup>nd</sup> paragraph.

The amended claim 20 also has overcome the previous rejections of 102(b) and 103 based on **Kazuo et. al.** (JP'657). However, the changed scope of claim 20 necessitates the following new ground(s) of rejection.

It is acknowledged that applicants have confirmed the election of Group 15 without traverse. Although the claims have been amended to formula (IIC), the definition of R<sup>1</sup>-R<sup>4</sup> still has non-elected subject matter.

Claims 1-19, 21-26, 28, 29 and 31-33 are cancelled.

Claims 20, 27, 30, and 34-40 are pending along with new claims 41-44.

### *Double Patenting*

The **nonstatutory double patenting** rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

Art Unit: 1624

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1. Claims 20, 30, 34-44 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9, 11 and 12 of U.S. Patent No. 6,593,333 B1 (commonly assigned). Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons:

a. Formula I of US'333 embraces the instant formula (IIC) when the variables in US'333 have the following meanings:

- i.  $R^1$  is  $C_{1-6}$ alkoxy,  $m = 2$  (which corresponds to the instant variables  $R^1$ - $R^4$ );
- ii. One of  $R^2$  and  $R^3$  is hydrogen and the other is halogen or alkyl (which corresponds to the instant variables  $R^7$  and  $R^8$ ).
- iii.  $R^4$  is K-J wherein K is a bond, and J is aryl, heteroaryl or heterocycle (which corresponds to the instant variable  $R^{64}$ ).
- iv. Note, compounds recited in claim 9 of US'333 read on the instant formula (IIC) as well.

Formula I of US'333 differs from the instant formula (IIC) by having only C(O), and not SO<sub>2</sub> group corresponding to the instant variable Z, and by having  $R^4$  representing more groups than the instant variable  $R^{64}$ . However, such a difference constitutes a situation of genus vs. subgenus. It would have been within the level of one skilled in the art to recognize that when Z

Art Unit: 1624

is C(O), then the instant formula (IIC) is a subgenus of formula I of US'333. Thus, it would have been obvious to select and make compounds of the instant formula (IIC) in view of formula I claimed in US'333.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 20, 27, 30, 34, 35 and 37-40 are rejected under 35 U.S.C. 102(b) as being anticipated by **Brown et. al.** (WO 96/15118).

On page 54, Brown et. al. discloses a compound in Example 11 which reads on the instantly claimed formula (IIC) with the following substituents:

- v.  $R^1$  and  $R^4$  are hydrogen atoms;
- vi.  $R^2$  and  $R^3$  – each represents  $X^1R^{15}$ ;
- vii.  $X^1$  is –O–, and  $R^{15}$  is an alkyl group (selected from group (1') of claim 20);
- viii. Z is CO;
- ix. One of  $R^7$  and  $R^8$  is halogen, and the other is hydrogen;
- x.  $R^{64}$  is phenyl;

Then, on page 59, Brown et. al. discloses compound #26<sup>2</sup> which reads on the instantly claimed formula (IIC) with the following substituents:

- xi. R<sup>1</sup> and R<sup>4</sup> are hydrogen atoms;
- xii. R<sup>2</sup> and R<sup>3</sup> – each represents X<sup>1</sup>R<sup>15</sup>;
- xiii. X<sup>1</sup> is –O–, and R<sup>15</sup> is an alkyl group (selected from group (1') of claim 20);
- xiv. Z is SO<sub>2</sub>;
- xv. One of R<sup>7</sup> and R<sup>8</sup> is halogen, and the other is hydrogen;
- xvi. R<sup>64</sup> is phenyl;

Note, the current proviso in claim 20 does not exclude such a compound since said proviso requires both R<sup>7</sup> and R<sup>8</sup> to be hydrogen atoms.

The process of making formula recited in the instant claim 27 is also taught in Example 11 on page 54 of WO'118. The process in Example 11 also starts with a substituted quinazoline (i.e., *4-chloro-6,7-dimethoxyquinazoline hydrochloride*) corresponding to the instant formula VIII, and a substituted aniline (i.e., *4-amino-2-chlorobenzanilide*) corresponding to the instant formula (IX').

The method of treating colorectal or breast cancer recited in the instant claim 44 is also taught in the third paragraph on page 42 of WO'118.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 1624

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
  2. Ascertaining the differences between the prior art and the claims at issue.
  3. Resolving the level of ordinary skill in the pertinent art.
  4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
3. Claims 20, 27, 30 and 34-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Brown et. al.** (WO'118). As discussed in the 102 rejection above, the two disclosed compounds reads on formula (IIC) when both R<sup>1</sup> and R<sup>4</sup> are hydrogen as recited in the instant claims 20, 27, 30, 34, 35, 37-40, and 44. However, they differ from a compound recited in the instant claims 36-43 by not having a substituent corresponding to the instant R<sup>4</sup> as "*halo, C<sub>1-4</sub>alkyl or C<sub>1-4</sub>alkoxy.*" Such a difference can be resolved by the generic definition of the reference's R<sup>1</sup> mentioned on page 4 of WO'118. In said definition, R<sup>1</sup> can be "*halogeno, ..., (1-4C)alkyl, (1-4)alkoxy, ...etc.*", and m can be 3. Therefore, besides the substitution on 6<sup>th</sup> and 7<sup>th</sup> positions, the quinazoline ring can also have a third substituent either at the 5<sup>th</sup> or the 8<sup>th</sup> position (corresponding to the instant R<sup>4</sup>). Thus, with such a generic teaching, the skilled chemist would

have been motivated to have 3 substituents on the quinazoline ring since such a modification would still maintain the same tyrosine kinase inhibitory properties.

Hence, at the time that the invention was made, it would have been obvious to make and use compounds of the instant formula (IIC) in view of the species and genus taught by Brown et. al.

No pending claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.



Art Unit: 1624

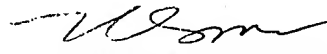
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tamthom N. Truong whose telephone number is 571-272-0676. The examiner can normally be reached on M-F (9:30-6:00).

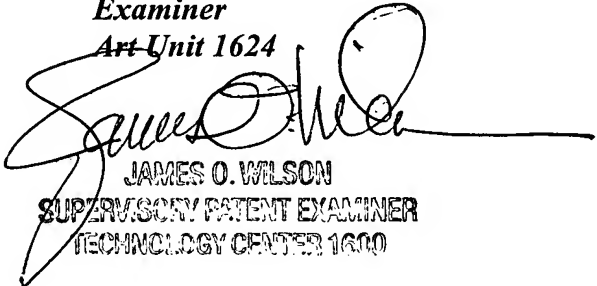
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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10-16-05

  
**Tamthom N. Truong**  
**Examiner**  
**Art Unit 1624**

  
**JAMES O. WILSON**  
**SUPERVISOR, PATENT EXAMINER**  
**TECHNOLOGY CENTER 1600**